ECHA and Biocides: Implementing the Roadmap to Phase Out Animal Testing

Workshop on implementing EC roadmap on phasing out animals in pesticides and biocides

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ECHA support to the roadmap

The roadmap is about transforming chemical safety assessment

ECHA role	Roadmap actions	Examples of ECHA involvement
Direct responsibility	2, 11, 15, 16, 21	Organise Collaborative Platform on Alternatives to Animal Testing (CP-AAT) (15, 16) Provide data on animal use outside the EU (21)
Technical and scientific contribution	5, 8, 14, 17, 20	Identify gaps in alternatives through Key areas of regulatory needs (KARN) reports (5)
Monitoring and strategic engagement	1, 3, 4, 6, 7, 9, 10, 12, 13, 18, 19, 22	Contribute the inventory of training resources and gaps (19)

… while maintaining a high level of protection for human health and the environment.

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ECHA's vision for the transition

1. **Identify regulatory needs**
2. **Apply available NAMs where fit for purpose**
3. **Rethink future assessment frameworks**
4. **Strengthen collaboration**

TODAY

Existing regulatory system

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HYBRID EVIDENCE BASE

Animal and non-animal evidence

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FUTURE

Integrated non-animal assessment framework

The transition is progressive: define needs, demonstrate usefulness and redesign the framework.

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What ECHA is already doing

The roadmap builds on ongoing activities rather than starting from zero.

1 Data sharing

Avoid duplicate animal testing

2 QSARs

Predictive in silico evidence

3 Read-across

Use information from related substances

4 Weight of evidence

Integrate multiple evidence streams

5 Collaboration

Coordinate alternative-method work

6 Capacity building

Training and stakeholder engagement

Ongoing work provides the practical foundation for roadmap implementation.

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Why implementation is challenging

Scientific, regulatory and practical questions must be resolved together.

SCIENTIFIC

Connect NAM outputs to biology and protection

- Represent systemic, chronic and life-stage effects
- Translate mechanism to adversity and concentration to relevant dose
- Integrate exposure, kinetics and effects
- Characterise applicability and uncertainty

REGULATORY

Decide when the evidence is sufficient

- Define transparent acceptance criteria
- Reach consistent conclusions across frameworks and jurisdictions
- Demonstrate that decisions maintain the required level of protection

PRACTICAL

Enable consistent application in assessments

- Standardise methods, reporting and data formats
- Provide accessible data, tools and guidance
- Build assessor expertise and regulatory experience

The challenge is to produce the regulatory outputs, protection level and confidence currently provided by the existing framework.

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Implications for the BPR

A progressive regulatory pathway

1

APPLY LAST RESORT

Vertebrate testing only as a last resort, after considering existing data and applicable adaptations.

2

USE NAM-SUPPORTED EVIDENCE

QSARs • ADME/TK • PBK modelling
In vitro approaches

3

IMPLEMENT GRADUALLY

No automatic change to BPR requirements. Start through guidance, scientific practice, validation and regulatory experience.

Evolution of evidence generation and assessment, with protection maintained.

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NAMs are already embedded in biocides assessment

BPR information requirements and adaptation rules already provide for non-animal evidence and tiered assessment.

HUMAN HEALTH

Local effects

In vitro and defined approaches

- Skin corrosion / irritation (e.g. TG 431, 439)
- Eye damage / irritation (e.g. TG 437, 492)
- Skin sensitisation (TG 442C–E, 497)

Genotoxicity

In vitro core data set

- Bacterial gene mutation (TG 471)
- Mammalian cytogenicity (TG 473, 487)
- Mammalian gene mutation (TG 476, 490)

Endocrine activity evidence

- ER, AR and steroidogenesis (TG 455, 458, 456)
- In silico predictions and WoE

Cross-cutting evidence

- QSAR and read-across
- ADME / TK and modelling
- Human and non-animal data

ENVIRONMENT

Fate and exposure

- Degradation and transformation (e.g. TG 301, 307–309)
- Adsorption, mobility and PECs

Non-vertebrate effects

Invertebrate tests still use animals

- Algal growth inhibition (TG 201)
- Aquatic invertebrate effects (e.g. TG 202, 211)

Bioaccumulation

- Intrinsic clearance as input to IVIVE/QSAR (TG 319 A and B)
- Tiered information generation
- HYBIT to be included in guidance (TG 321)

Metabolites and ED

- ER and AR transactivation, and steroidogenesis (TG 455, 458, 456)
- QSAR / read-across
- In silico screening and WoE
- XETA in the annex to ECHA EFSA ED guidance (TG 248)

STANDARD REQUIREMENT → INTEGRATED ASSESSMENT → VERTEBRATE TESTING ONLY WHERE STILL NECESSARY

NAM implementation builds on an existing BPR regulatory foundation.

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NAM-related evidence discussed in Biocidal product committee (BPC) Working groups (WGs)

HUMAN HEALTH

Read-across and transformation

- Read across proposed for TK, repeated-dose, reproductive, carcinogenicity and ED endpoints
- In vitro gastric-fluid degradation used to support hypothesis

In silico and in vitro endocrine evidence

- QSAR and OECD Toolbox predictions
- ER and AR transactivation and other mechanistic assays

PBK modelling

- Internal dose and target-organ metrics
- Dermal exposure and MoIE refinement

ENVIRONMENT

QSARs for metabolites

- Ecotoxicity predictions
- Corrected predictions accepted by ENV WG

PNEC refinement

- Parent assessment covered metabolite except groundwater
- Additional assessment factor removed; revised PNECs agreed

Fate and exposure modelling

- Corrected QSAR affected Koc-related assessment inputs
- Separate groundwater assessment remained necessary

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Where NAM-related evidence has not yet been sufficient in BPC WGs

The recurring difficulty is connecting submitted evidence to a complete and reliable regulatory conclusion.

HUMAN HEALTH

Read-across: biological equivalence

- TK equivalence and relevant species not sufficiently demonstrated
- Quantitative relationship to adverse effects remained uncertain

PBK: model confidence

- Key studies not fully integrated
- Sensitivity, uncertainty and validation insufficient

Endocrine modalities

- E-modality considered sufficiently investigated
- Further evidence required for A/S modalities

ENVIRONMENT

Model applicability

- Correct molecular structure and inputs are essential
- Corrected predictions required re-evaluation

Compartment-specific exposure

- Accepted metabolite QSARs did not remove groundwater assessment
- Persistence and mobility required separate consideration

Evidence still incomplete

- Some cases still require additional data
- Study design can limit the conclusion

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Extending NAM use towards more complex conclusions

The roadmap builds from established uses towards integrated non-animal assessment, endpoint by endpoint.

ESTABLISHED USE	DEVELOPING USE	REMAINING CHALLENGES
Human health • Skin and eye in vitro methods • Skin-sensitisation defined approach • In vitro genotoxicity • Selected endocrine activities	**Human health** • In vitro ADME / TK • PBK and QIVIVE • Quantitative read-across	**Human health** • Repeated-dose and systemic toxicity • Reproductive and developmental toxicity • Chronic toxicity and carcinogenicity
Environment • Fate and exposure data • Algae and invertebrate effects • QSAR / read-across for metabolites	**Environment** • Fish-cell assays (non-animal) • In vitro clearance • Mechanistic environmental ED	**Environment** • Chronic fish toxicity • Cross-species extrapolation • Population and ecosystem protection

A mixed evidence base supports progress towards integrated non-animal assessment.

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Main takeaway messages

1. **The goal is to phase out animal testing while strengthening the scientific basis of safety assessment and maintaining protection of human and animal health and the environment.**

2. **The transition requires regulatory confidence, not only new methods.**

3. **For biocides, progress means building on existing NAM use and addressing the remaining gaps together, while maintaining protection of human and animal health and environment.**

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